

1893.03(d) (2005): “Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371.”)

The M.P.E.P. also provides guidance as to when claims possess unity of invention:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. *Note also the examples contained in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from WIPO's web site ([www.wipo.int/pct/en/texts/gdlines.htm](http://www.wipo.int/pct/en/texts/gdlines.htm)).*

M.P.E.P. 8<sup>th</sup> ed., rev. 4, § 1893.03(d) (2005) (emphasis added) (*see also* M.P.E.P. 8<sup>th</sup> ed., rev. 4, Appendix AI- Administrative Instructions Under the PCT, Annex B Unity of Invention, paragraph (I) (2005): “Examples giving guidance on how these [unity of invention] principles may be interpreted in particular cases are set out in the PCT International Search and Preliminary Examination Guidelines.”)

The PCT International Search and Preliminary Examination Guidelines provide an example of protein and nucleic acid claims that possess unity of invention:

*Example 39: Protein and its Encoding DNA*

*Claim 1: Isolated protein X having SEQ ID NO: 1.*

*Claim 2: Isolated DNA molecule encoding protein X of claim 1.*

...

*The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO:1.*

*There is no prior art.*

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

PCT International Search and Preliminary Examination Guidelines, Chapter 10, page 96 (emphasis in original). Examples 32, 33, 36 and 37 on pages 91-95 of these guidelines also suggest that unity of invention exists amongst homologous sequences of a novel and inventive sequence. Hence, claims directed to a novel and unobvious protein (or its homologous forms) and the encoding nucleic acid possess unity of invention and should be examined together.

#### ***Applicants' Special Technical Feature***

Applicants respectfully assert that the special technical feature unifying the claims is the protein given by SEQ ID NO: 10. Because this special technical feature is novel and unobvious, claims directed to this protein and its encoding nucleic acids possess unity of invention and must be examined together.

#### ***Claims 30-40, 43 and 44 Possess Unity of Invention***

The Examiner has alleged that claims 30-33, 37-39 and 43 belong in Group I, and that claims 34-36, 40 and 44 belong in Group II. Restriction Requirement, page 2. The reason for the separation of these claims is provided on the following page: "The special technical feature of Group I is the nucleotide sequence of a nucleic acid encoding a given protein from *Ostertagia ostertagi*. The special technical feature of Group II is the specific amino acid sequence of a given protein and the biochemical and immunological properties of said protein." Restriction Requirement, page 3.

However, the subject matter of these claims is akin to that of Example 39 of Chapter 10 of the International Search and Preliminary Examination Guidelines. *Supra*.

Because these claims are directed to a novel and inventive protein (or 90% homologous proteins) and their encoding nucleic acids, the claims possess unity of invention and their restriction is improper. Hence, Applicants respectfully request that the Examiner reconsider and withdraw the Restriction Requirement as it pertains to these claims.

***Claims 41 and 42 Possess Unity of Invention with Claims 30-40, 43 and 44***

The Examiner has also alleged that claims 41 and 42 belong in Group III. Restriction Requirement, page 2. These claims are alleged to belong in a separate group from the claims discussed above because “[t]he special technical feature of Group III is the specific combination of a protein from *Ostertagia ostertagi* and an additional antigen.” Restriction Requirement, page 3.

Applicants respectfully assert that these claims do not belong in a separate group because they are dependent upon claims of Group I or II. The M.P.E.P. provides specific guidance regarding claims that are dependent upon claims possessing unity of invention:

**(c) Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) *If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims.* In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. *Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.*

M.P.E.P. 8<sup>th</sup> ed., rev. 4, Appendix AI- Administrative Instructions Under the PCT, Annex

B Unity of Invention (2005) (emphasis added). Hence, claims that are dependent upon claims that possess unity of invention should be kept within the same group, as they also possess unity of invention.

Here, the Examiner alleges that claims 41 and 42 belong in Group III because they represent a specific combination. Applicants respectfully assert that the M.P.E.P. provides guidance that such claims should not be partitioned into a separate group, and request that the Examiner reconsider and withdraw this aspect of the Restriction Requirement.

***Claims 45-49 Possess Unity of Invention with Claims 30-44***

The Examiner has alleged that each of claims 45-49 belong in one of Groups IV-VI. Restriction Requirement, page 2. In particular, the Examiner explains that these claims belong in separate groups because “[t]he special technical feature of each of Groups IV-VI is the specific active steps and reagents used in each method.” *Id.* at page 3.

For the reasons discussed above (and wholly incorporated here), claims 45-49 do not belong in separate groups *because they are dependent* upon one or more of claims 30-44, which possess unity of invention.

Moreover, claims 45-49 are directed to a method of preventing or treating an infection caused by *Ostertagia ostertagi* in an animal by administering an effective amount of a vaccine product identified in one or more of claims 30-44. U.S. Patent Regulations explicitly state that such claims possess unity of invention:

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

...

(2) A product and process of use of said product; . . .

37 C.F.R. § 1.475(b)(2). Because claims 45-49 relate to claims 30-44 according to this regulation, they possess unity of invention with claims 30-44 and should be examined together. Accordingly, Applicants respectfully request that the Examiner reconsider and

withdraw the Restriction Requirement as it relates to claims 45-49.

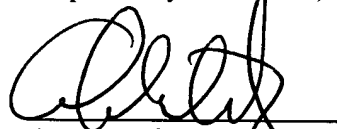
*Conclusion*

If the Restriction Requirement is not withdrawn or is only partially withdrawn, Applicants respectfully request that the Examiner make the requirement final, so that Applicant may petition the Director to review the requirement. *See* 37 C.F.R. § 1.144.

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

Applicants submit that this application is in condition for allowance, and request that it be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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